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<p>(21) International Application Number: PCT/US00/13254 (22) International Filing Date: 15 May 2000 (15.05.00) (30) Priority Data: 60/134,141 14 May 1999 (14.05.99) US (71) Applicant: SUTURA, INC. [US/US]; 17080 Newhope Street, Fountain Valley, CA 92708 (US). (72) Inventors: NOBLES, Anthony, R.; 8686 Tern Avenue, Fountain Valley, CA 92708 (US). CREW, John, R.; 255 Moncada Way, San Francisco, CA 94127 (US). (74) Agent: NATAUPSKY, Steven, J.; Knobbe, Martens, Olson & Bear, LLP, 16th floor, 620 Newport Center Drive, Newport Beach, CA 92660-8016 (US).</p>		<p>(81) Designated States: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CZ, CZ (Utility model), DE, DE (Utility model), DK, DK (Utility model), DM, DZ, EE, EE (Utility model), ES, FI, FI (Utility model), GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SK (Utility model), SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).</p> <p>Published <i>Without international search report and to be republished upon receipt of that report.</i></p>
<p>(54) Title: KNOT PUSHER</p> <p>(57) Abstract</p> <p>A knot pusher for pushing suture knots (200) towards an incision in a vessel or an organ of a patient includes an elongate member (124) which engages the knots. One segments (194) of the suture is attached to a suture leader (100) which pulls the segment (194) through a lumen in the elongate member (124). Consecutive knots are advanced towards the incision by pushing the knots with the elongate member (124), while holding one or both ends of the suture.</p>		

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KNOT PUSHERBackground of the InventionField of the Invention

The invention relates to suturing incisions, and more specifically, to the use of sutures for closing incisions in vessels and organs within a body.

Description of the Related Art

Surgeons frequently encounter the need to close incisions, wounds, or otherwise join tissue portions with a suture. After passing the suture through the tissue portions, the surgeon must tie the suture to draw the tissue portions together and prevent them from separating. When sutures are tied in a region having restricted access, such as the end of a tissue tract leading to an artery, the surgeon is presented with special challenges. Typically, the knot is formed outside the patient and then is pushed towards those tissue portions to be joined together with the end of the surgeon's finger. This technique is cumbersome, time consuming, and leads to uncertain results. A more reliable procedure is needed whereby a surgeon can rapidly and accurately draw tissue portions towards each other and complete the knot.

Summary of the Invention

One aspect of the invention is an apparatus for pushing a knot formed in a suture. The apparatus includes an elongate member having a distal end portion and a lumen through at least the distal end portion. The lumen is sufficiently small to prevent the knot from passing through the distal end portion, but is sufficiently large to permit an unknotted segment of suture to pass through the distal end portion. The apparatus also includes a suture leader having a distal end portion sized for insertion into an opening in the elongate member and sized for passage through at least a portion of the lumen such that at least the distal end portion of the suture leader extends out of the lumen. The suture leader is adapted to releasably secure the suture thereto such that withdrawal of the suture leader from the lumen draws the suture into the lumen. In a preferred embodiment of the apparatus, the suture leader comprises a twisted wire, and the distal end portion of the suture leader comprises a grasping portion for receiving the suture segment. The apparatus may further comprise a cutter having an elongate body, in which the cutter includes a cutting element for cutting the suture segment, and the cutter is slidable along the elongate member.

Another aspect of the invention is a method of suturing, which includes advancing a length of suture through tissue portions such that first and second suture segments extend from the tissue portions. An elongate member is provided, at least a portion of which comprises a tube. The first suture segment is drawn through at least a portion of the tube. A first knot is tied in the suture using the first and second suture segments. The tube is advanced over the first suture segment, and a distal portion of the tube is used to push the first knot towards the tissue portions. A second knot is tied in the suture using the first and second suture segments, and the tube is advanced over at least one of the first and second suture segments to push the second knot towards the first knot. In a preferred embodiment of

the method, drawing the first suture segment includes advancing a suture leader through the tube, securing the suture leader to the first suture segment, and withdrawing the suture leader from the tube. The suture leader may be withdrawn from a proximal end portion of the tube, or alternatively, from an opening in a distal end portion of the tube. In one preferred embodiment, advancing a length of suture through the tissue portions comprises extending the first and second suture segments through a catheter sheath introducer (CSI).

Yet another aspect of the invention is a method of suturing, which includes providing a suture having two free ends, providing an elongate member having a lumen through at least a portion thereof, and drawing a first end segment of the suture through at least a portion of the lumen. A knot is formed using the two free ends of the suture by (i) using a second end segment to form an upper loop which passes in front of the first end segment, and (ii) using the second end segment to form a lower loop that extends from the upper loop behind the first end segment, and in one embodiment, passes in front of the second end segment. The elongate member is used to push the lower loop along the first end segment such that the upper loop is pulled by the lower loop along the first end segment. Preferably, at least one additional knot is formed and pushed against the previous knot.

Brief Description of the Drawings

FIGURE 1 shows a suture leader comprising a handle and a wire.

FIGURE 2 shows an end view of the handle of FIGURE 1 which has two holes therein for receiving the ends of the wire.

FIGURES 3A and 3B show perspective and cross sectional views of a holder and a tubular member of the first knot pusher embodiment, which are preassembled.

FIGURE 4 shows the first knot pusher embodiment with the suture leader.

FIGURES 5-9 illustrate how the knot pusher embodiment of FIGURES 1-4 is used to push one or more knots towards an incision within a patient.

FIGURE 10 is a schematic illustration showing the interaction of the suture with a knot pusher.

FIGURE 10A is a schematic illustration showing the interaction of the suture with a knot pusher, in which the suture is in the form a clinch knot.

FIGURES 11 and 11A show a suture cutter which can be used in combination with the knot pusher embodiments disclosed herein to cut back the ends of the suture.

FIGURE 11B shows the suture cutter of FIGURE 11A cutting the ends of the suture.

FIGURES 12A and 12B illustrate a tubular member and a holder of a second knot pusher embodiment.

FIGURE 13 shows the second knot pusher embodiment with a suture leader.

FIGURE 14 illustrates how the knot pusher embodiment of FIGURE 13 is used to push one or more knots towards an incision within a patient.

FIGURE 15 shows a suture cutter used in combination with the knot pusher embodiment of FIGURE 13.

FIGURE 15A shows the suture cutter of FIGURE 15 cutting the ends of the suture.

Detailed Description of the Preferred Embodiment

Preferred embodiments of the invention are shown and described with respect to the accompanying figures. As shown in FIGURE 1, a suture leader 100 comprises a handle 101 having an annular portion 102 and a cylindrical base portion 104. The handle 101 may be made of polypropylene. The annular portion 102 and the cylindrical portion 104 together may extend about 1.5" in the longitudinal direction. The cylindrical portion 104 may have an outside diameter (O.D.) of 0.38" and has double lead $\frac{1}{4}$ turn threads 106 on its interior surface, as seen in FIGURE 2.

The handle 101 is connected to a wire retainer 110 which is comprised of a loop of relatively stiff, but flexible wire. The wire 110 is twisted so as to form an elongate double wire structure. The ends of the wire 110 are inserted into respective holes 112 (see FIGURE 2) in the cylindrical portion 104 of the handle 101 and are bonded to the handle using an adhesive such as cyanoacrylate. The wire 110 may be 0.010" stainless steel, such as spring steel. Before bonding the wire 110 to the handle 101, it may be necessary to roughen the surface of the wire so that a suitably strong bond between the handle and the wire can be formed. For example, the ends of the wire 110 may be knurled using knurling arbors in a knurling press or a vice to form a roughened surface on the wire. A distal portion of the twisted wire structure 110 comprises a grasping portion 120, which in the preferred embodiment comprises a capture loop 120. In the preferred embodiment, the loop 120 is diamond-shaped, and preferably has a small sub-loop at the distal end of which acts as a spring to bias the capture loop 120 open.

FIGURES 3A and 3B show a tubular, elongated extrusion member 124. A proximal end portion of the tubular member 124 fits snugly within a lumen extending through a holder 130. The tube 124 may be comprised of a polymer such as polycarbonate, and may be 9.7" long with a lumen therein which has an inside diameter (I.D.) of 0.031" along the entire length of the tube. The outside diameter of the tube 124 may be 0.095" at its proximal end, and beginning about 0.85" from the distal end 140 of the tube 124, taper down to an O.D. of about 0.060". The diameter of the lumen is constant along the length of the holder 130 and is slightly greater than about 0.095". The tube 124 and the holder 130 may be joined to each other by ultrasonic welding or by an adhesive such as cyanoacrylate to form an integrated unit. The proximal end of the tube 124 is flush with the proximal end of the holder 130, as indicated in FIGURE 3B. The holder 130 may be polypropylene.

The holder 130 has threads 150 on its exterior surface that mate with the threads 106, permitting the holder 130 to be screwed into the cylindrical portion 104 of the handle 101. In this way, the holder 130/tube 124 unit and suture leader 100 may be assembled to form a knot pusher assembly 160, as illustrated in FIGURE 4. The capture loop 120 of the suture leader 100 (FIGURE 1) has, in its relaxed state, a width substantially greater than that of the tube 124 so that the physician can easily thread the suture therein. However, the wire 110 of which the capture loop 120 is formed is sufficiently flexible to allow it to flatten so that the wire 110 can be threaded into and through the lumen of the tube 124. The length of the wire retainer 110 is chosen such that the capture loop 120 extends slightly beyond the distal end of the tube 124. The wire 110 is sufficiently resilient to allow the capture loop 120 to return to its original relaxed configuration when outside the confines of the tube 124.

FIGURE 5 shows a catheter sheath introducer (CSI) 170 that has been introduced through an incision 174 in the patient's skin, e.g., a leg 180 of the patient. A suture 190 has been introduced into the patient for the purpose of drawing together tissue portions 195, 196 (shown in phantom in FIGURE 5). Two end segments 192, 194 of the suture 190 extend from the tissue portions 195, 196, respectively, which may, for example, be the result of a wound or an internal incision in a blood vessel or organ. The suture 190 may be introduced into the patient in any suitable manner, including those described in U.S. Patent 5,860,990 entitled "Method and Apparatus for Suturing", Applicant's copending application 09/231,177 filed January 14, 1999 entitled "Suturing Device for Sealing Artery Following Angiogram", and Applicant's copending application 09/524,211 filed March 13, 2000 entitled "Suturing Device and Method," all of which are hereby incorporated by reference herein. The suture 190 may be 0.007" diameter biodegradable material or non-biodegradable material such as polypropylene.

As illustrated in FIGURE 6, in the assembled device 160, the wire retainer 110 is threaded through the tube 124 so that the grasping portion 120 of the wire 110 extends beyond the distal end of the tube 124. The practitioner slips one segment (e.g., segment 194) of the suture 190 between the wires that form the grasping portion 120. In order to move the suture leader relative to the tube 124, the handle 101 is rotated to unscrew the threaded engagement with the tubular member 124. Next, with reference to FIGURES 7 and 8, while holding the segment 192 with one hand, the handle is then pulled to draw the wire 110 from the tubular member 124 in the proximal direction. As the suture leader 100 is pulled proximally to draw the suture into the tube 124, the inner walls of the tube compress the grasping portion 120 so that the wire portions that form the grasping portion pinch the suture therebetween and hold the segment 194 securely enough such that the wire 110 can be removed from the tube 124 without dislodging the suture segment 194 from the grasping portion 120. In such manner, the segment 194 of the suture 190 is drawn into and through the tube 124.

As shown in FIGURES 7 and 8, the lumen within the tube 124 is sufficiently large to permit the suture segment 194 and the wire 110 to pass through the entire length of the lumen. Once the wire 110 is pulled all the way through the tube 124, the suture 190 may be detached from the grasping portion 120 by pulling on the suture. The wire 110 and the handle 101 thus guide the suture segment 194 through the tube 124. Although shown and described herein with respect to the wire grasping portion 120, the suture 190 may be secured by any pair of facing members adapted to pinch a suture segment therebetween, especially resiliently biased facing members.

The practitioner may then form a surgical knot out of the suture 190, typically a self-cinching knot which can be slid towards the incision to cinch the tissue portions together. The inside diameter of the lumen within the tubular member 124 is substantially smaller than the knot, and thus the knot is too large to enter the lumen. Accordingly, as shown in FIGURE 9, the tubular member 124 may be used to push the knot 200 through the CSI 170, towards and up against the internal incision. Preferably, the tube 124 is advanced against the knot 200 with one hand, while both segments 192, 194 of the suture 190 are held with the other hand. The tapered contour of the tube 124 near its distal end 140 facilitates the pushing of the knot 200 along the tissue tract and reduces any trauma or abrasion that

would be produced by a blunt end. Bleedback through the lumen in the tubular member 124 provides the user with an indication as to when the tubular member has been advanced sufficiently forward to close the opening being sutured.

The procedure outlined above should be repeated to add additional knots to lock the first knot in place. Preferably, 2-5 self-cinching knots, are pushed down one on top of another to provide a compound knot that provides secure closure. Once the incision is closed, the suture 190 may be cut back so that no strands are left dangling outside the patient. To this end, the suture 190 may be cut below the skin level with surgical scissors or with a cutter located at the distal end of the tube 124.

Although various types of knots may be used, one preferred method of using the knot pusher involves forming a compound knot 200 which starts with two consecutive half hitches 200 of the same kind (e.g., two right hitches or two left hitches). One segment of the suture 190 (e.g., the segment 194) is drawn through the tube 124 while the other segment (e.g., segment 192) remains outside of the tubular member 124. The two half hitches of the same type are tied in the suture. These half hitches are pushed towards the incision by advancing the tubular member 124 over the suture segment 194. During such advancing, tension is applied to the suture segment 194, which is held firmly in the hand of the practitioner, but no tension is applied to segment 192. In this manner, the two half hitches are pushed towards and up to the internal incision. Next, a single half hitch of the same type is formed (e.g., if two right half hitches were initially used, then a single right half hitch is formed) and pushed towards and up to the internal incision with the tubular member 124, but with the practitioner now holding both segments 192, 194 securely in one hand, as in FIGURE 9, with some tension on both segments. All consecutive knots are of the same type, except for the last knot. The last knot is a half hitch of the other type or orientation, e.g., if the previous knots were all right half hitches, then a left half hitch is used, thereby creating a square knot.

Referring to FIGURE 10, one embodiment of the slidable tubular member 124 has a tapered distal end with a very small diameter. This configuration is advantageous for sliding the knot 200 towards the patient. As illustrated, the surgical knot 200 may be formed by suture segments 192, 194 with the tubular member 124 slidably mounted on the segment 194. The suture segment 192, as viewed from FIGURE 10, has a lower loop portion 210 which crosses underneath the segment 194, and an upper loop portion 212 which loops on top of the segment portion 194 and above and behind the portion 210. (For ease of illustration, the suture is shown as broken in two places to show that other suture portions pass over it; however, it will be understood that the suture is a continuous strand.)

The tip 214 of the tapered end portion of the tubular member 124 engages the intersection of the portion 210 and the suture segment 194, with the loop portion 212 passing above and in front of such tip 214. Thus, the tapered end of the member 124 is surrounded by the upper loop portion 212 such that the tip 214 is effectively embedded within the knot 200. In this position, the tip 214 pushes the knot 200 at the lower intersection of the suture segment portions 192, 194 (i.e., at the intersection of the lower loop portion 210 and the suture segment portion 194). Accordingly, the knot 200 is pushed from the bottom portion of the knot rather than the top portion of the knot. This permits the knot 200 to be easily advanced toward the patient, and prevents the knot from tightening prematurely due to interaction with the knot pusher.

Another type of knot 200 that is preferred for use with the tubular member 124 is the clinch knot shown in FIGURE 10A. As illustrated, the knot includes the upper loop portion 212 and the lower loop portion 210. However, the lower loop portion has a serpentine portion extending from it, an end of which passes through a loop in the segment 192. As discussed above, several of these knots are successively pushed towards the incision using the tube 124 to form the compound knot 200'. Once a tightened knot has been formed proximal to the internal incision (e.g., in accordance with one of the methods described herein), the excess suture material is cut off.

One technique for cutting the suture 190 is illustrated with respect to FIGURES 11, 11A, and 11B. Both segments 192, 194 of the suture 190 are pulled through the tubular member 124. A suture cutter 220 is inserted into and slides within (i.e., is pushed through) the tube 124 towards the secure compound knot 200' (FIGURE 11B) which is preferably just proximal the internal incision or tissue portions to be joined. The cutter 220 includes an elongate body having a proximally pointing cutting element 224 such as a blade (see FIGURE 11A) at a distal end portion of the elongate body, with the cutting element being situated a predetermined distance, e.g. 1 cm, from the distal end of the cutter 220. The cutter 220 is pushed as far as possible towards the secure knot 200', so that the cutting element 224 is about 1 cm from the knot. The user can then cut the suture 190 by either retracting or rotating the cutter 220 so that the cutting element 224 slices through both strands of the suture, as shown in FIGURE 11B. As an alternative to configuring the suture cutter 220 with the cutting element 224, say, 1 cm from the distal end of the cutter, the cutting element may be placed at the distal end of the cutter and a mark (not shown) or a stop (not shown) on the cutter 220 may act as an indicator to the user that the cutter should not be advanced further. If desired, a sheath (not shown) may be used to surround the suture cutter 220 to minimize the risk of incidental damage to the patient, with the sheath being retracted just prior to the suture 190 being cut by the cutter.

Another knot pusher embodiment is shown in FIGURES 12A, 12B, and 13. This embodiment comprises a tubular member and utilizes a suture leader similar to those shown in FIGURE 1. However, the tubular member and the holder to which the tubular member is joined are configured differently from their counterparts in FIGURES 3A and 3B. FIGURES 12A and 12B show a tubular member 124a which includes a distal end 140a and an opening 230 near the distal end. The tubular member 124a is secured to a holder 130a. As shown by the assembled device 160a of FIGURE 13, the wire retainer 110a is passed into the opening 230, and through only the distal end 140a, rather than through and along the entire length of the tubular member 124a. Further, the suture leader 100a is not attached to the proximal end of the holder 130a, which obviates the need for threads 150 in the holder. Likewise, the wire 110a of FIGURES 13 and 14 may be short compared to the wire 110 utilized in the first knot pusher embodiment shown in FIGURES 1 and 8.

One preferred method of using the embodiment of FIGURE 13 is shown with respect to FIGURE 14. As illustrated, the suture segment 194 is drawn into the lumen of the tubular member 124a and out of the opening 230 using the wire 110a. The user then forms self-cinching knots, such as the half hitch shown in FIGURE 10 or the clinch knot shown in FIGURE 10A. In one exemplary embodiment, the user forms two half hitches of the same orientation (e.g., two right hitches or two left half hitches, but not one left half hitch and one right half hitch) and then holds the

segment 194 taught in one hand while simultaneously holding the CSI 170 with the same hand. With his other hand, the user pushes the knot 200 (in this case, the two half hitches) with the tubular member 124a down the CSI 170 and towards the internal incision. Next, a single half hitch of the same type is formed (e.g., if two right half hitches were initially used, then a single right half hitch is formed) and pushed towards and up to the internal incision with the tubular member 124a, but with the practitioner now holding both segments 192, 194 and the CSI 170 securely in one hand, while pushing the tubular member 124a with his other hand. All consecutive knots are advanced in an analogous fashion towards the internal incision and are likewise of the same type, except the last knot. The last knot is a half hitch of the other type, e.g., if the previous knots were all right half hitches, then a left half hitch is used, thereby creating a square knot. Although the foregoing procedure utilizes half hitches, it will be understood that the compound knot 200' may be formed using any of a variety of other types of knots. In any case, the embodiment of FIGURE 13 can be easily utilized by a single practitioner throughout the entire procedure. Further, the suture 190 does not need to be as long as the suture in the embodiment of FIGURE 4, since the segment 194 of the suture now exits the opening 230 and does not extend along the entire length of the tubular member 124a.

With a fully formed compound knot just proximal to the internal incision, the user then proceeds to cut back the suture so that the segments 192, 194 do not extend out of the incision 174 in the patient's skin. The suture cutter 220 of FIGURES 11 and 11A may be used for this purpose. The suture segments 192 and 194 are passed through the tubular member 124a (e.g., the suture end 194 may be passed through the hole 230 and the suture end 192 passed along the entire length of the tubular member 124a), and the suture cutter 220 is then placed inside the tubular 124a and pushed towards the secure knot. With the cutting element 224 near the knot, the cutting element is retracted or rotated, thereby cutting the suture 190. By butting the tubular member 124a against the knot and positioning the cutting element 224 distal to the opening 230, the cutting element cuts through the segment 194 of the suture 190 as well as the segment 192.

Alternatively, as shown in FIGURE 15, a hypotube 250 having sharpened edges 254 at its distal end may be prepositioned over the tubular member 124a. After the compound knot at the internal incision is formed, both suture ends 192, 194 are drawn through the opening 230. The distal end of the tube 124a is positioned within the CSI 170 adjacent the compound knot 200', and the hypotube 250 is urged towards the knot (i.e., the hypotube slides over the tubular member 124a). The edges 254 of the hypotube 250 sever the segments 192 and 194 of the suture 190, as illustrated in FIGURE 15A. (For clarity of illustration, the CSI 170 is not shown in FIGURE 15A so as to expose the compound knot 200' and distal portion of the tube 124a.) A mark (not shown) on the tubular member 124a may be used to gauge how far forward the practitioner should push the hypotube 250. Also, a detent mechanism (not shown), may be used to hold the hypotube 250 to the holder 130a when the hypotube 250 is not being used.

Various embodiments of the present invention have been described above. Although this invention has been described with reference to these specific embodiments, the descriptions are intended to be illustrative of the invention and are not intended to be limiting. Various modifications and applications may occur to those skilled in the art without departing from the true spirit and scope of the invention as defined in the appended claims.

WHAT IS CLAIMED IS:

1. An apparatus for pushing a knot formed in a suture, comprising:
an elongate member having a distal end portion, said elongate member having a lumen through at least said distal end portion, said lumen being sufficiently small to prevent the knot from passing through said distal end portion, said lumen being sufficiently large to permit an unknotted segment of suture to pass through said distal end portion; and
a suture leader having a distal end portion sized for insertion into an opening in said elongate member and through at least a portion of said lumen such that at least said distal end portion of said suture leader extends out of said lumen, said suture leader adapted to releasably secure the suture thereto such that withdrawal of said suture leader from said lumen draws the suture into said lumen.
2. The apparatus of Claim 1, wherein said distal end portion of said suture leader comprises a grasping portion for receiving the suture segment.
3. The apparatus of Claim 1, wherein said lumen extends through the entire length of said elongate member.
4. The apparatus of Claim 1, wherein said suture leader comprises a twisted wire.
5. The apparatus of Claim 4, comprising a handle attached to said wire.
6. The apparatus of Claim 1, wherein said opening in said elongate member is disposed between proximal and distal ends of said elongate member, said opening sized to allow passage of said distal end portion of said suture leader into said lumen.
7. The apparatus of Claim 1, further comprising a cutter having an elongate body, said cutter including a cutting element for cutting the suture segment, said cutter being slidable along said elongate member.
8. The apparatus of Claim 7, wherein said elongate body slides within said lumen.
9. The apparatus of Claim 7, wherein said elongate body slides over said elongate member.
10. The apparatus of Claim 1, said distal portion of said suture leader comprising a pair of pinching members adapted to pinch the suture segment therebetween.
11. The apparatus of Claim 10, wherein said pinching members are resiliently biased to hold the suture therebetween while permitting said suture to be released therefrom by pulling on the suture.
12. A method of suturing, comprising:
advancing a length of suture through tissue portions such that first and second suture segments extend from the tissue portions;
providing an elongate member, at least a portion of which comprises a tube;
drawing the first suture segment through at least a portion of the tube;
tying a first knot in the suture using the first and second suture segments;
advancing the tube over the first suture segment and using a distal portion of the tube to push the first knot towards the tissue portions;

tying a second knot in the suture using the first and second suture segments; and
advancing the tube over at least one of the first and second suture segments to push the second
knot towards the first knot.

13. The method of Claim 12, wherein the second knot is tied while the first segment is in said portion
of the tube.

14. The method of Claim 12, wherein said advancing the tube over at least one of the first and second
suture segments comprises advancing the tube over the first suture segment.

15. The method of Claim 12, wherein said drawing the first suture segment includes:
advancing a suture leader through the tube;
securing the suture leader to the first suture segment; and
withdrawing the suture leader from the tube.

16. The method of Claim 15, wherein said withdrawing said suture from the tube comprises
withdrawing the suture leader from a proximal end portion of the tube.

17. The method of Claim 15, wherein said withdrawing said suture from the tube comprises
withdrawing the suture leader from an opening in a distal end portion of the tube.

18. The method of Claim 12, comprising:
tying a knot having an orientation opposite to that of a previously tied knot; and
advancing the knot of opposite orientation towards the previously tied knot to form a square knot.

19. The method of Claim 12, wherein said advancing a length of suture through the tissue portions
comprises extending the first and second suture segments through a catheter sheath introducer (CSI).

20. The method of Claim 19, comprising holding both the first suture segment and the CSI with one
hand while advancing the tube with another hand.

21. The method of Claim 12, wherein the tissue portions are portions of a blood vessel.

22. The method of Claim 12, wherein the second suture segment is left outside of the tube while the
tube is advanced over the first suture segment.

23. The method of Claim 12, further comprising cutting the first and second suture segments after the
second knot has been pushed towards the first knot by sliding a cutter along the tube towards the tissue portions.

24. The method of Claim 23, comprising sliding the cutter through the tube.

25. The method of Claim 23, comprising sliding the cutter over the elongate member.

26. A method of suturing, comprising:
providing a suture having two free ends;
providing an elongate member having a lumen through at least a portion thereof;
drawing a first end segment of said suture through at least a portion of the lumen;

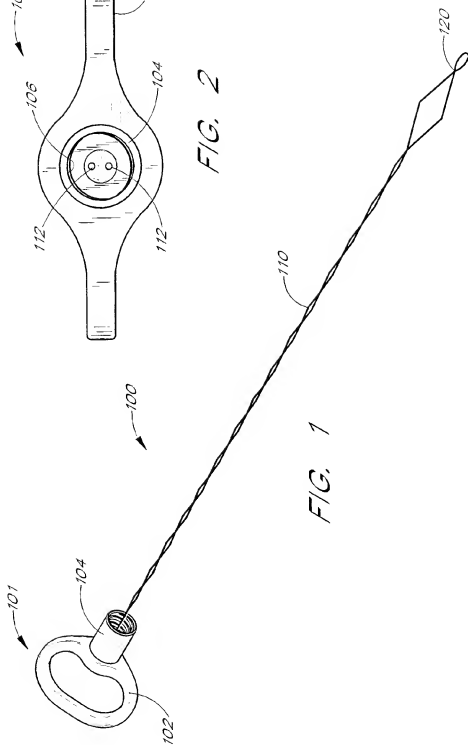
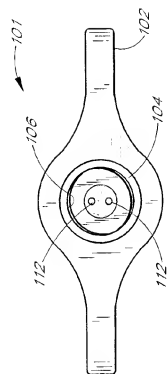
forming a knot using the two free ends of the suture, said forming comprising (i) using a second end segment to form an upper loop which passes in front of the first end segment and (ii) using said second end segment to form a lower loop that extends from the upper loop behind the first end segment; and

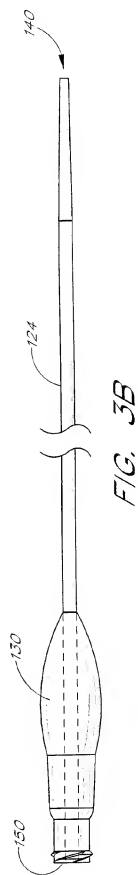
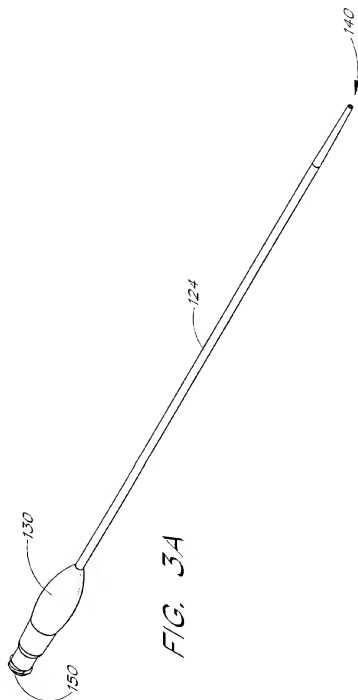
using the elongate member to push the lower loop along the first end segment such that the upper loop is pulled by the lower loop along the first end segment.

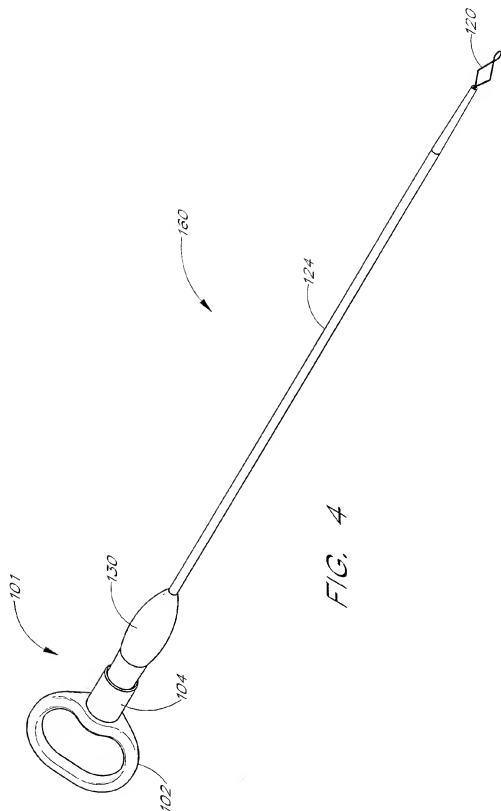
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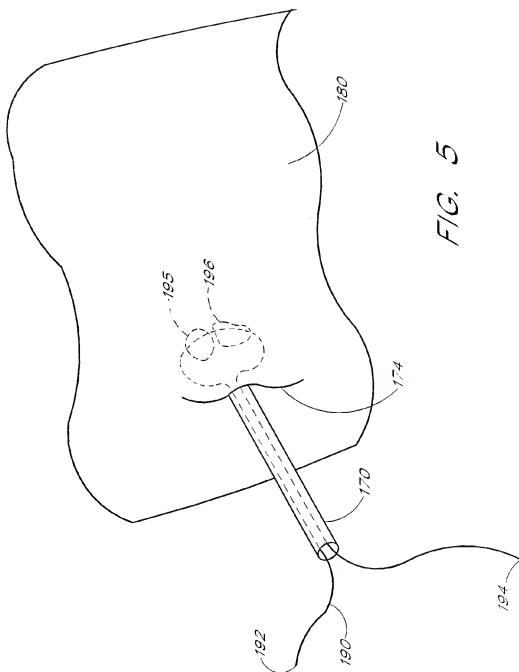
27. The method of Claim 26, wherein the lower loop passes in front of the second end segment.

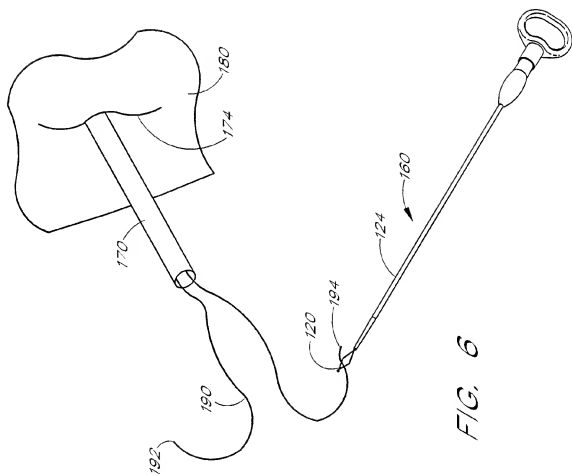
28. The method of Claim 26, wherein a serpentine portion is formed at an end of the lower loop portion.

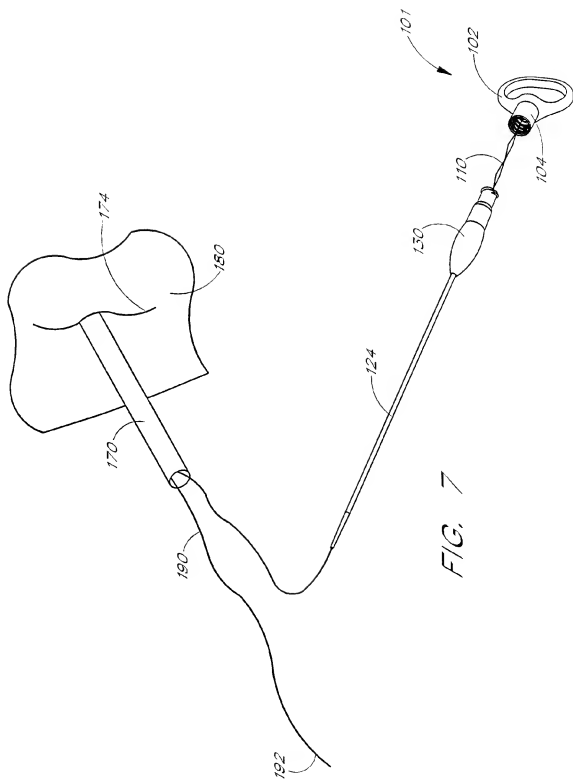












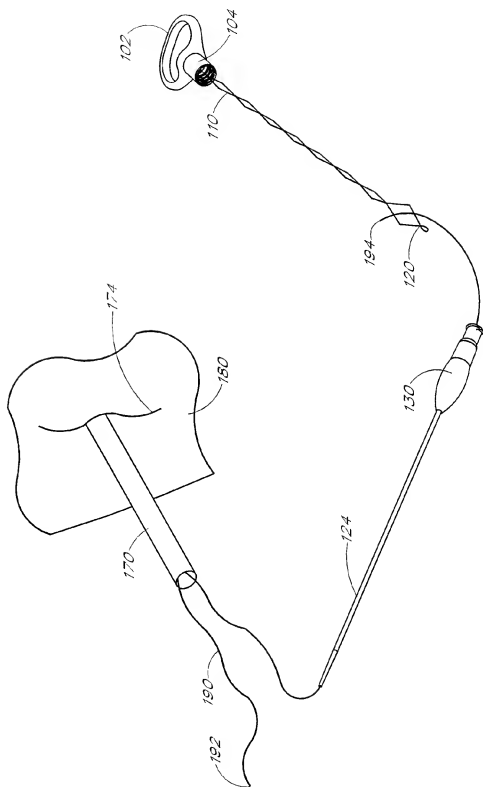
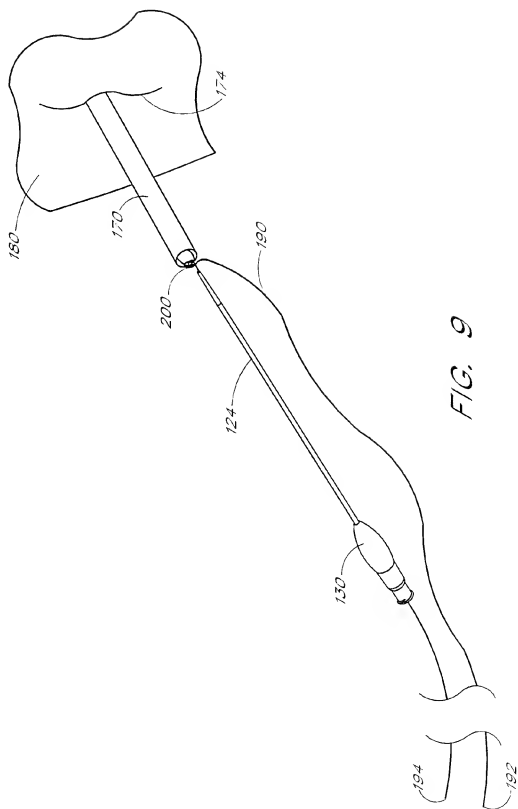


FIG. 8



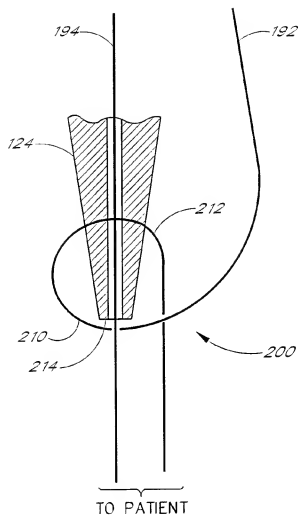
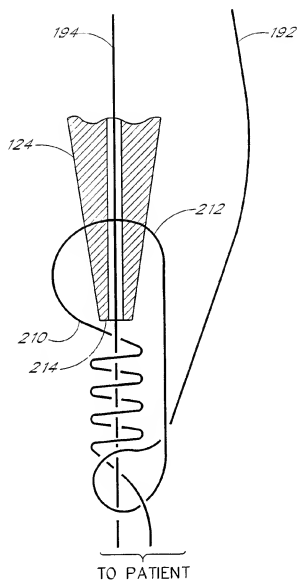


FIG. 10

*FIG. 10A*

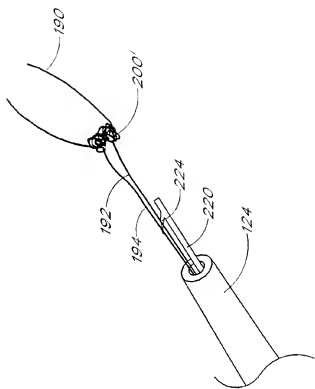
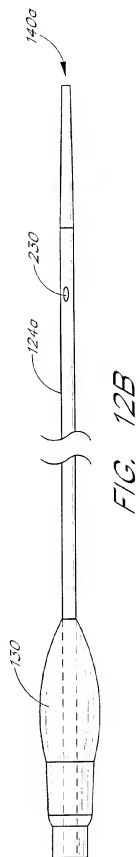
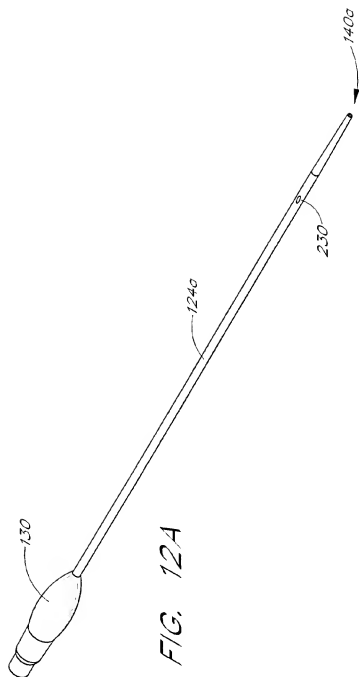
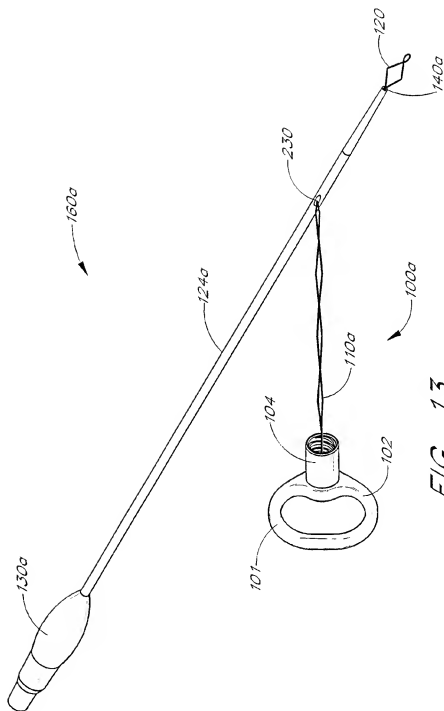
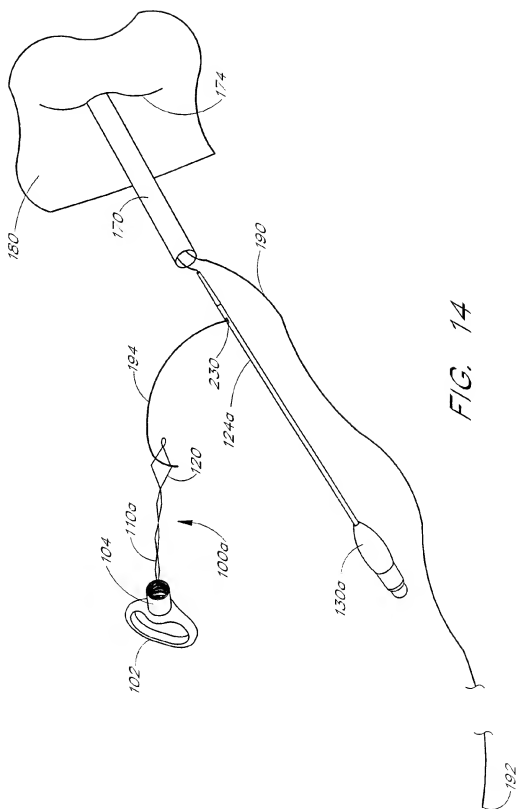


FIG. 11B





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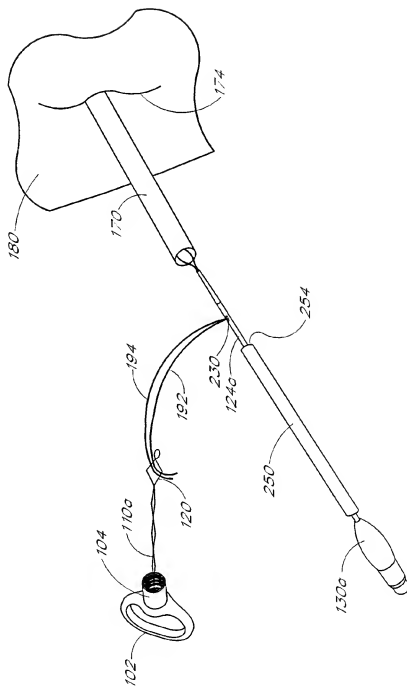
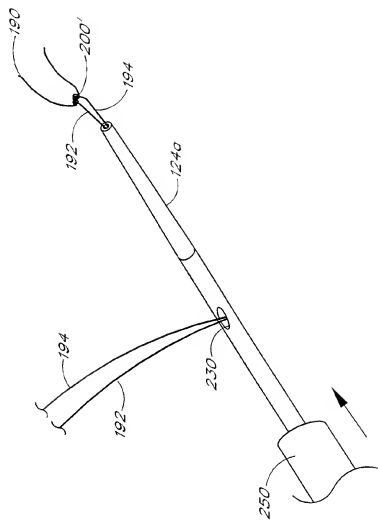


FIG. 15



INTERNATIONAL SEARCH REPORT

Intern^o Application No
PCT/US 00/13254**A. CLASSIFICATION OF SUBJECT MATTER**
IPC 7 A61B17/04

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EP0-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 746 752 A (BURKHART STEPHEN S) 5 May 1998 (1998-05-05) the whole document ---	1-3,6, 10,11
A	US 5 709 692 A (MOLLENAUER KENNETH H ET AL) 20 January 1998 (1998-01-20) column 4, line 54 -column 5, line 60; figure 4 ---	1,4,5
A	DE 29 00 265 A (SAMMER FRITZ DR) 17 July 1980 (1980-07-17) the whole document ---	1,4,5
A	US 5 718 725 A (STEVENS JOHN H ET AL) 17 February 1998 (1998-02-17) abstract; figures 9,13 --- -/-	1,7-9

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Date of the actual completion of the international search

7 November 2000

Date of mailing of the international search report

21/11/2000

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INTERNATIONAL SEARCH REPORT

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PCT/US 00/13254

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 752 964 A (MERICLE ROBERT W) 19 May 1998 (1998-05-19) abstract; figures 4,10-12 ---	1,7-9
A	US 5 466 241 A (LEROY JOEL ET AL) 14 November 1995 (1995-11-14) abstract; figure 9 ---	1
A	US 5 217 470 A (WESTON PETER V) 8 June 1993 (1993-06-08) abstract; figures 19,20 -----	1

INTERNATIONAL SEARCH REPORT

Information on patent family members

Intern Application No

PCT/US 00/13254

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5746752 A	05-05-1998	NONE	
US 5709692 A	20-01-1998	US 5562685 A WO 9608202 A	08-10-1996 21-03-1996
DE 2900265 A	17-07-1980	JP 55094247 A	17-07-1980
US 5718725 A	17-02-1998	US 5571215 A US 5452733 A US 5433700 A US 5725496 A US 5795325 A US RE35352 E US 5814097 A US 5762624 A US 6027476 A US 5713951 A US 5728151 A US 5682906 A US 5766151 A US 6010531 A US 6029671 A US 6125852 A US 5814016 A US 5972030 A AU 702940 B AU 1099595 A CA 2177490 A EP 0732890 A JP 9509585 T WO 9515715 A US 5613937 A US 5797960 A US 6079414 A US 5855614 A US 5823956 A US 5829447 A US 5980455 A US 5924424 A AU 688303 B AU 6024594 A CA 2154354 A EP 0684781 A JP 8511694 T WO 9418881 A US 5425705 A US 5569274 A US 5735290 A US 5536251 A US 5799661 A US 5961481 A US 5855210 A	05-11-1996 26-09-1995 18-07-1995 10-03-1998 18-08-1998 15-10-1996 29-09-1998 09-06-1998 22-02-2000 03-02-1998 17-03-1998 04-11-1997 16-06-1998 04-01-2000 29-02-2000 03-10-2000 29-09-1998 26-10-1999 11-03-1999 27-06-1995 15-06-1995 25-09-1996 30-09-1997 15-06-1995 25-03-1997 25-08-1998 27-06-2000 05-01-1999 20-10-1998 03-11-1998 09-11-1999 20-07-1999 12-03-1998 14-09-1994 01-09-1994 06-12-1995 10-12-1996 01-09-1994 20-06-1995 29-10-1996 07-04-1998 16-07-1996 01-09-1998 05-10-1999 05-01-1999
US 5752964 A	19-05-1998	NONE	
US 5466241 A	14-11-1995	FR 2704132 A AT 160493 T DE 69406972 D	28-10-1994 15-12-1997 08-01-1998

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No.

PCT/US 00/13254

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5466241 A		DE 69406972 T DK 621007 T EP 0621007 A ES 2112495 T GR 3026226 T	02-07-1998 10-08-1998 26-10-1994 01-04-1998 29-05-1998
US 5217470 A	08-06-1993	NONE	